

P A T E N T

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re:	Jill McFadden et al.	Confirmation No.:	2472
Serial No.:	09/097,023	Examiner:	Elizabeth R. Moulton
Filing Date:	June 12, 1998	Group Art Unit:	3767
Docket No.:	1001.1566101	Customer No.:	28075
For:	CATHETER WITH KNIT SECTION		

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Commissioner for Patents
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REPLY BRIEF UNDER 37 C.F.R. § 41.41

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The undersigned hereby certifies that this paper or papers, as described herein, are being electronically transmitted to the U.S. Patent and Trademark Office on this 1st day of July 2009.

By 
Kathleen L. Bockley

Dear Sir:

Pursuant to 37 C.F.R. § 41.41, Appellants hereby submit this Reply Brief in response to the Examiner's Answer mailed on May 20, 2009. Remarks begin on page 2.

REMARKS

This paper is prepared in reply to the Examiner's Answer of May 20, 2009. Appellants agree with the Examiner's statements in paragraphs 1-8 and 11 of the Examiner's Answer. For the reasons stated below, Appellants disagree with the Examiner's statements in paragraphs 9 and 10 of the Examiner's Answer.

Response to Examiner's Arguments

Inconsistent and Inaccurate Usage of "Braid" and "Knit"

Appellants firstly object to the Examiner's inconsistent and inaccurate usage of the terms "braid" and "knit" throughout the Examiner's Answer. Appellants assert that a braided member has a distinct interwoven configuration from that of a knitted member. As addressed in Appellants' Appeal Brief, the component of Samson denoted as Ref. No. 244 is an inner braid of the catheter shown in FIG. 7, having a structure not equivalent to that of a knitted member.¹ Additionally, contrary to statements made in the Examiner's Answer such as "Anderson's [sic] braid is equivalent to appellant's braid"², Andersen teaches a radially expandable knitted stent, not a braid. Furthermore, the disputed element of Appellants' claimed invention is a knit tubular member which is generally not radially expandable formed of a single strand forming a plurality of up loops interlocked with a plurality of down loops, not a braid as indicated in the above quotation taken from the Examiner's Answer at page 4. Appellants maintain that the dissimilarities between a braided member and a knit member as currently claimed are not insignificant.

The Stent of Andersen is Radially Expandable

In response to Appellants' argument that the knitted stent of Andersen is radially expandable, the Examiner opined that "the braid [sic] of Anderson [sic] would be constrained by the liner when used in the invention of Samson so it would not expand radially."³ Appellants disagree. In interpreting claims during examination, "limitations therein are to be interpreted in

¹ See Appeal Brief of April 8, 2009, at page 8.

² Examiner's Answer of May 20, 2009, at page 4.

³ Examiner's Answer of May 20, 2009, at page 4.

light of the specification in giving them their 'broadest reasonable interpretation'."⁴ "When the applicant states the meaning that the claim terms are intended to have, the claims are examined with that meaning, in order to achieve a complete exploration of the applicant's invention and its relation to the prior art."⁵

Each of claims 51 and 52 states that the knit tubular member is generally not radially expandable. As defined in the Specification, this means that the knit tubular member "does not increase in diameter more than about 5% when an outwardly directed radial force is applied to an inner surface of the knit member."⁶ As described in the present application, one aspect of the claimed knit tubular member is to act as a stiffener in the wall of the catheter, allowing the walls of the catheter tube to be made thinner compared to walls of catheters having equal strength but made solely of polymeric materials.⁷ Thus, the knit tubular member itself contributes to restraining radial expansion of the distal segment of the catheter, as the knit tubular member itself is generally not radially expandable. In other words, the knit tubular member contributes to the hoop strength of the catheter wall.

As noted above, the term "generally not radially expandable" requires that the knit tubular member not increase in diameter more than about 5% when an outwardly directed radial force is applied to an inner surface of the knit tubular member. In other words, the structural limitation of being generally not radially expandable applies to the knit tubular member independent of any structural environment that the knit member is incorporated in.⁸ The definition requires an outwardly directed radial force be directly applied to the inner surface of the knit tubular member to determine its radial expandability or non-expandability.

Disregarding Appellants' intended meaning for this claim limitation, the Examiner erroneously suggests that the radially expandable and contractible stent of Andersen becomes "generally not radially expandable" when included in the structure of the catheter of Samson. The Examiner's argument is flawed. The Examiner's position requires the liner of Samson to be the radially non-expandable member, restraining radial expansion of the catheter, not the

⁴ M.P.E.P. §2111.01 II., quoting *In re Marosi*, 710 F.2d 799, 802, 218 USPQ 289, 292 (Fed. Cir. 1983).

⁵ *In re Zletz*, 893 F.2d 319, 321-22, 13 USPQ2d 1320, 1322 (Fed. Cir. 1989).

⁶ Specification, at lines 17-20 of page 8.

⁷ Specification, at lines 18-22 of page 3.

⁸ Note that neither claim 51 nor claim 52 affirmatively recites any structural component exterior of the knit tubular member which would constrain the knit tubular member from radial expansion in the event the knit tubular member was not "generally not radially expandable."

expandable knitted stent of Andersen. The expandable knitted stent of Andersen would be ineffective for restraining radial expansion of the catheter. Namely, the expandable knitted stent is not constructed to be "generally not radially expandable."⁹ In fact, Andersen expressly describes the knitted stent as an "elastic knitted stent".¹⁰ In the event the liner could not withstand the full extent of an outwardly directed radial force exerted on the catheter, the expandable knitted stent of Andersen would be of no avail to oppose the radial force. The expandable knit stent of Andersen would simply expand when subjected to the radially outward force. Thus, the wall of the catheter of Samson would be required to be sized to withstand the full radial force with the understanding that the expandable knitted stent would not contribute to the hoop strength of the catheter wall, resulting in a thicker catheter wall. Therefore, the presence of the expandable knitted stent of Andersen in the catheter of Samson would increase the wall thickness of the catheter without contributing to the hoop strength of the catheter wall.

There is No Rationale to Combine the Stent of Andersen in the Catheter of Samson

Appellants disagree with the Examiner's suggestion that it would have been obvious to incorporate the expandable knitted stent of Andersen in the catheter of Samson. As the Supreme Court pointed out in *KSR Int'l Co. v. Teleflex Inc.*, "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art."¹¹ Rather, the Court stated:

[I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does...because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known.¹²

The Court further stated that the obviousness inquiry requires a determination of "whether the improvement is more than the predictable use of prior art elements according to their established

⁹ Note Appellants' arguments presented in the Appeal Brief of April 8, 2009, at pages 8-10, where the Appellants demonstrate that the knitted stent of Andersen is radially expandable and contractible in order to allow peristaltic movement of the stent in a peristaltic organ without the stent migrating within the organ.

¹⁰ Andersen, at line 33 of column 5.

¹¹ *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007).

¹² *Id.* at 418-419 (emphasis added).

functions” and “whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.”¹³

Appellants maintain that the expandable knitted stent of Andersen does not function as the claimed knit tubular member does, thus not motivating one of skill in the art to provide a catheter including a knit tubular member which is generally not radially expandable in the fashion currently claimed. Moreover, one of skill in the art, at the time of Appellants' invention, would not consider the expandable knitted stent of Andersen as an alternative to the braid of the catheter of Samson.

The expandable knitted stent of Andersen is intended to reinforce the lumen of a peristaltic organ while accommodating peristalsis of the organ by locally expanding and contracting without migrating in the organ.¹⁴ Andersen states, “A stent for an organ like the esophagus, according to the invention, not only holds the lumen open but allows the organ to maintain its physiologic motion.”¹⁵ The elastic nature of the knitted stent of Andersen pushes radially outward on the lumen wall while the loosely interlocked rows of loops may shift axially relative to and independent of adjacent rows to accommodate local expansion and compression of the stent.¹⁶

Thus, it can be seen by one of ordinary skill in the art that the established function of the expandable knitted stent of Andersen is quite different from the braid of the catheter of Samson. As stated in Samson, “[t]he superelastic alloy braid is, in its most basic form, a braid comprising a number of small superelastic alloy ribbons wound and treated in such a way that the resulting braid is dimensionally stable and the ribbons do not twist.”¹⁷ Thus, the teachings of Samson indicate that the diameter of the braid should be unvarying throughout its usage in a catheter. One of skill in the art would not be motivated to substitute the dimensionally stable braid structure of Samson with a structure (e.g., the expandable knitted stent of Andersen) that is readily expandable and contractible between a range of diameters to accommodate peristaltic motion. The Examiner's stated motivation to substitute the expandable knitted stent of Andersen

¹³ Id. at 418 (emphasis added).

¹⁴ See Andersen, at Abstract.

¹⁵ Andersen, at lines 27-29 of column 5.

¹⁶ See Andersen, at lines 47-49 of column 3, lines 40-42 of column 4, lines 25-26 of column 5, and lines 22-23 of column 6.

¹⁷ Samson, at lines 64-67 of column 7.

for the braid of the catheter of Samson cannot be arrived at without following a reconstructive hindsight analysis, explicitly prohibited in an obviousness determination.¹⁸

Conclusion

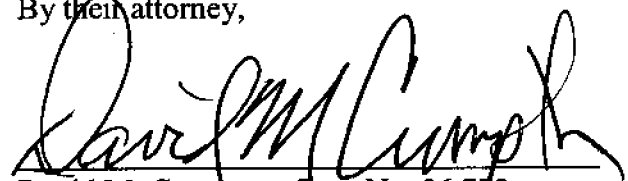
For the reasons provided in Appellants' Appeal Brief, as well as those stated above, the rejections of claims 51 and 52 based on the teachings of Samson and Andersen et al. should be reversed.

Respectfully submitted,

Jill McFadden et al.

By their attorney,

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¹⁸ See *Sensonics, Inc. v. Aerosonic Corp.*, 81 F.3d 1566, 1570, 38 USPQ 2d 1551, 1554 (Fed. Cir. 1996), ("The invention must be viewed not after the blueprint has been drawn by the inventor, but as it would have been perceived in the state of the art that existed at the time the invention was made.")